



December 13, 2023

Kenneth Burdick,
Chief Executive Officer, WellCare Health
Centene Plaza
700 Forsyth Boulevard
St. Louis, MO 63105
Kenneth.burdick@wellcare.com

Sarah London
Chief Executive Officer, Centene Corporation
Centene Plaza
7700 Forsyth Boulevard
St. Louis, MO 63105
mediainquiries@centene.com
slondon@centene.com

Via Electronic Communication

Re: Double-Step Fail-First Policies Harm Health Care Consumers

Dear Mr. Burdick and Ms. London:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. The Movement Disorders Policy Coalition (MDPC) serves as a platform from which stakeholders, including health care providers and patients, can provide input on policy decisions impacting patient-centered care for those living with movement disorders. Jointly, we are reaching out to express our concerns regarding WellCare’s double-step fail-first policy for patients with tardive dyskinesia. Step therapy policies that require patients to try and fail on multiple medications before accessing their originally prescribed treatment force patients to endure ongoing symptoms without relief and can result in irreversible disease progression.

Tardive dyskinesia (TD) is a movement disorder that causes individuals to experience repetitive and involuntary movements in their arms, neck, legs, or face.¹ TD often occurs as a side effect of long-term medication, such as anti-psychotics, and can become permanent even after an individual has stopped taking the TD-causing medication.² TD is common in individuals living with Parkinson’s disease and schizophrenia.³ While anyone can develop TD, older adults; females; and individuals who smoke, have substance use disorder, or uncontrolled diabetes are more likely to develop TD.⁴ Fortunately, there are Food and Drug Administration (FDA) approved treatments to reduce the symptoms and impact of TD. However, benefit utilization policies, such as step-therapy, that are overly burdensome and inconsistent with clinical practice guidelines harm patients with TD and can contribute to avoidable disease progression.

¹ NAMI, *Tardive Dyskinesia*, [https://www.nami.org/About-Mental-Illness/Treatments/Mental-Health-Medications/Tardive-Dyskinesia#:~:text=Tardive%20dyskinesia%20\(TD\)%20is%20a,significantly%20affecting%20quality%20of%20lif](https://www.nami.org/About-Mental-Illness/Treatments/Mental-Health-Medications/Tardive-Dyskinesia#:~:text=Tardive%20dyskinesia%20(TD)%20is%20a,significantly%20affecting%20quality%20of%20lif)

² *Id.*

³ *Id.*

⁴ *Id.*

Step-therapy policies, often known as “fail first,” require patients to try and fail on alternative treatments, sometimes causing adverse effects, before the plan will cover the originally prescribed treatment.⁵ Such policies can be unethical and inconsistent with standards of care, interfering with the patient-provider relationship and compromising patient health outcomes.

The American Psychological Association (APA) recommends that patients with TD be treated with VMAT2 inhibitors such as deutetrabenazine or valbenazine.⁶ Both deutetrabenazine or valbenazine are FDA approved to treat TD.⁷ The APA guidelines further state that both of these treatments are recommended over tetrabenazine because tetrabenazine has a shorter half-life and may increase rates of depression in some patients.⁸ Moreover, unlike deutetrabenazine or valbenazine, tetrabenazine is not FDA approved to treat TD.⁹

Despite the APA’s recommendations, WellCare’s fail-first policy requires patients with TD to try and fail on deutetrabenazine and tetrabenazine before being able to access valbenazine. This policy is inconsistent with the APA’s clinical practice guidelines for the treatment of TD. Moreover, because tetrabenazine is not FDA approved to treat TD, it is considered an off-label use of the drug. While off-label treatment may be appropriate in certain cases, this decision should be left to the health care provider’s professional judgement, not mandated by the plan. Furthermore, requiring patients to try-and-fail on two treatments could lead to patients experiencing irreversible disease progression, challenges maintaining treatment compliance for the underlying mental health condition, and increased social anxiety.

Therefore, Aimed Alliance and MDPC urge WellCare to revise its double-step fail-first policy and remove the two-step requirement for patients living with TD. We would greatly appreciate an opportunity to meet with your team to discuss our concerns surrounding this policy and its impact on patients. Please contact us at avantrees@aimedalliance.org if you have any questions. We look forward to your response.

Sincerely,

Ashira Vantrees
Counsel, Aimed Alliance

Movement Disorder Policy Coalition

⁵ Aimed Alliance, *Step Therapy*, <https://aimedalliance.org/step-therapy/>

⁶ American Psychiatry Association, *Practice Guideline for the Treatment of Patients with Schizophrenia, 3rd Ed.*, <https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890424841>.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*